

**RESPONSE UNDER 37 CFR §1.116
EXPEDITED PROCEDURE EXAMINING GROUP 1634**

REMARKS

The instant invention relates to generally to "protection of telomere-1," or "Pot 1" proteins. As described in the instant specification, Pot 1 proteins bind single-stranded telomeric DNA, thereby stabilizing chromosome ends and regulating telomerase activity. In particular, functional variants, and in particular splice variants, of human Pot 1 are described and claimed in the present application.

Claims 6-48 are currently pending in the instant application with claims 1-5 being cancelled without prejudice and claims 6-36 being withdrawn by the Examiner from consideration. Claims 37-48 are currently under examination. By the present communication, Applicants have cancelled claims 6-36, and amended claims 37-48. The amendments simply clarify the claimed invention using preferred terminology and are fully supported by the specification. No new matter is introduced or new search is required. In particular, high stringency hybridization conditions are defined in the specification, e.g., in the paragraph bridging pages 25 and 26.

Applicants respectfully submit that the foregoing amendments comply with the Examiner's requirement, place the instant application in better form for appeal, and that, therefore, entry of the amendments at this time is proper.

Notwithstanding the foregoing, Applicants expressly reserve the right to prosecute subject matter no longer or not yet claimed in the instant application or in one or more applications which may claim priority hereto. Applicants respectfully request reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

Atty. Dkt. No. 089491-0201
RESPONSE UNDER 37 CFR §1.116
EXPEDITED PROCEDURE EXAMINING GROUP 1634

Non Art-Related Remarks

35 U.S.C. § 112, First Paragraph

Applicants respectfully traverse the rejection of claims 37, 40, 41, 44, 45, 46, and 47 under 35 U.S.C. § 112, first paragraph, as alleged containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time of filing..

The proper standard by which compliance with the written description requirement of 35 U.S.C. § 112, first paragraph, should be measured is whether the specification conveys with reasonable clarity to one of skill in the art that applicants had possession of the claimed invention. The subject matter need not be described literally in the specification to meet this reasonableness standard. *See*, MPEP § 2163.02.

The Examiner has acknowledged that hPot 1 proteins encoded by SEQ ID NOS: 15 and 17 meet the written description standard. Thus, claims 38, 39, 42, and 43 are not subject to the present rejection. In an effort to reduce the issues on appeal, Applicants have amended these claims so as to not depend from a rejected claim.

Moreover, as Applicants discussed in detail in the previous response filed on July 19, 2002, Applicants respectfully disagree with the Examiner's assertion that the specification does not meet the written description standard for any additional hPot 1 variants other than those of SEQ ID NOS: 15 and 17. As discussed in the Patent and Trademark Office *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶1, "Written Description" Requirement*, 66 Fed. Reg. 1099 (2001) (hereinafter "the Guidelines"), an adequate written description "may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. 66 Fed. Reg. at 1105 (emphasis added). For a genus, the Guidelines indicate that an adequate written description may be provided "by disclosure of relevant, identifying

Atty. Dkt. No. 089491-0201
RESPONSE UNDER 37 CFR §1.116
EXPEDITED PROCEDURE EXAMINING GROUP 1634

characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." *Id.* at 1106.

In the present case, Applicants have defined a genus of proteins that contain substantial sequence homology to one another, and that exhibit an unambiguous functional characteristic -- the ability to bind to single-stranded telomeric DNA. While Applicants disagree with the Examiner's assertions that the rejected claims do not provide any meaningful structural limitations to the claims, and include variants that do not have the ability to bind single stranded telomeric DNA, Applicants have amended claims 37, 40, and 44 to better define the claimed invention for the benefit of the Examiner.

Specifically, claim 37 as amended describes a human Pot 1 polypeptide that (i) is encoded by a polynucleotide that hybridizes under stringent conditions to a specified DNA sequence; and that (ii) binds single-stranded telomeric DNA. Similarly, claims 40 and 44 as amended describe a human Pot 1 polypeptide that (i) has at least 85% amino acid sequence identity to a specified amino acid sequence; and that (ii) binds single-stranded telomeric DNA. Applicants respectfully submit that the structure and function defined in these claims unambiguously defines the claimed human Pot 1 polypeptides, and that the specification conveys with reasonable clarity to one of skill in the art that applicants had possession of the invention as presently claimed.

Applicants respectfully submit that the foregoing amendments to the claims render moot the rejection under 35 U.S.C. § 112, first paragraph. Applicants, therefore, respectfully request that the Examiner reconsider and withdraw this rejection.

35 U.S.C. § 112, Second Paragraph

Applicants respectfully submit that the foregoing amendments to the claims render moot the rejection of claims 38-45 and 47-48 under 35 U.S.C. § 112, Second Paragraph as allegedly

**RESPONSE UNDER 37 CFR §1.116
EXPEDITED PROCEDURE EXAMINING GROUP 1634**

being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants, therefore, respectfully request that the Examiner reconsider and withdraw this rejection.

Art Related Remarks

35 U.S.C. §102 (b)

Applicants respectfully traverse the rejection of claims 37, 40, 41, 44, 45-48 under 35 U.S.C. §102(b), as allegedly being anticipated by Isogai (Accession No. BAA91568, February 22, 2000).

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teaching of the specification. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 199); See also MPEP 2131.

The Examiner states that the Isogai publication discloses a protein having an amino acid sequence identical to the protein of SEQ ID NO: 13, comprising an amino acid sequence identical to the protein of SEQ ID NO: 5, and comprising an amino acid sequence having at least 93% identity with SEQ ID NO: 15 and at least 96% identity with SEQ ID NO: 17. Applicants note that the Isogai publication does not disclose any isolated protein *per se*. Rather, the Isogai publication discloses a sequence obtained from a "human cDNA sequencing project" that putatively encodes a protein having an unknown function. See, Isogai, "TITLE." Nevertheless, in an effort to reduce issues and advance prosecution, the present claims have been amended to explicitly state that the protein of SEQ ID NO: 13 is not within the scope of the claims.

Furthermore, as Applicant has explained previously, the present claims relate to functional variants, and in particular splice variants, of human Pot 1 having a specific set of structural and functional characteristics. Applicants respectfully submit that the skilled artisan would have no motivation to seek variants of this published sequence having the claimed

Atty. Dkt. No. 089491-0201
RESPONSE UNDER 37 CFR §1.116
EXPEDITED PROCEDURE EXAMINING GROUP 1634

structural and functional characteristics, as no known function had yet been ascribed to this bare cDNA-derived sequence.

Applicants respectfully submit that the Isogai publication neither teaches or suggests the claimed polypeptides. Applicants, therefore, respectfully request that the Examiner reconsider and withdraw the rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Respectfully submitted,

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FOLEY & LARDNER
Customer Number: 30542
P.O. Box 80278
San Diego, California 92138-0278
Telephone: (858) 847-6700
Facsimile: (858) 792-6773

By 

For Richard J. Warburg
Michael A. Whittaker
Attorneys for Applicant
Registration No. 46,230